REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks. Claims 27-31 are new, and are supported for example by page 19, lines 20-23 and page 45, line 13 to page 49, line 10. Claims 23-31 are pending.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being obvious over Hashimoto et al. (WO 02/44167). Applicants respectfully traverse the rejection.

The rejection refers to page 8, lines 15-23, page 3, lines 15-23 and page 14, lines 1-5 and contends that the claimed elements of the process of producing an amorphous optically active isomer of lansoprazole are disclosed, and one would perform the drying step at various temperature ranges during the process of routine experimentation with a reasonable expectation of success of producing an amorphous optically active isomer of lansoprazole. However, Hashimoto merely mentions only once in the entire disclosure that the starting material may be a solid that is amorphous, and fails to provide any reason to expect that an amorphous optically active isomer of lansoprazole could be produced from hydrated crystals of optically active isomer (R-isomer) of lansoprazole. In fact, Hashimoto suggests just the opposite.

In particular, Hashimoto teaches that the solid described on page 8, lines 15-23, which may be crystal or amorphous, is obtained from a racemic mixture, as opposed to hydrated crystals of optically active isomer (R-isomer) of lansoprazole (see page 5, line 25 to page 8, line 17). Hashimoto teaches that the solid obtained from the racemic mixture can be a crystal that is a hydrate, and that this hydrated crystal shows specific peaks under X-ray powder diffraction analysis as described on page 9, line 30 to page 10, line 10. Hashimoto further teaches that this hydrated crystal can be recrystallized by transforming this hydrated crystal into crystals showing specific peaks under X-ray powder diffraction analysis as described on page 14, line 30 to page 15, line 10 (see page 11, line 2 to page 12, line 14 and page 14, line 30 to page 15, line 10). Although Hashimoto teaches that the hydrated crystal is dried during the recrystallization process (page 14, line 25), Hashimoto clearly indicates that the product obtained at the end of this drying process is a crystal exhibiting specific peaks under X-ray powder diffraction analysis (page 14, line 28 to page 15, line 10). Thus, it is clear from this description that Hashimoto teaches that a solid can be obtained from a racemic mixture, that this solid can be amorphous or a crystal that is a hydrate, and this solid can be converted into a crystal exhibiting specific peaks under X-ray powder diffraction analysis. Nothing in Hashimoto indicates that the crystalline solid is

converted into an amorphous optically active isomer. In fact, the reference teaches just the opposite to that of claim 23; that is, the reference teaches that after drying the amorphous solid, crystals exhibiting specific peaks under X-ray powder diffraction analysis are obtained.

Hashimoto further teaches that the recrystallized product exhibiting specific peaks under X-ray powder diffraction analysis is then partitioned and crystallized, and that the partitioned and crystallized products are dried, but the partitioned and crystallized products are not hydrated crystals. Specifically, Hashimoto teaches dissolving the recrystallized product in C_{1-4} alkyl acetate and adjusting the concentration of (R)-lansoprazole by partitioning the mixture and concentrating the organic layer by removing the water layer (page 17, line 16 to page 18, line 32 and page 40, lines 10-16). In the crystallization step, a solution containing C_{1-4} alkyl acetate (good solvent) and C_{5-8} hydrocarbon (poor solvent) is used (page 18, line 33 to page 19, line 17). No water is introduced during the crystallization step. Thus, the separated crystal obtained after partitioning and crystallizing is not a hydrated crystal, and as such, this crystal does not correspond to the hydrated crystal of claim 23. Nothing in Hashimoto indicates that the partitioned and crystallized crystal can be a hydrated crystal. Accordingly, claim 23 and its dependent claims are patentable over Hashimoto.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being obvious over Fujishima et al. (WO 00/78745). Applicants respectfully traverse the rejection.

The rejection refers to page 2, line 32 to page 3, line 3 and contends that Fujishima teaches that the starting material is a crystal of R(+)-lansoprazole which may be a hydrate. However, the reference is directed to forming a stable crystal of R(+)-lansoprazole (see page 1, lines 20-24; page 1, line 28 to page 2, line 15; page 2, lines 32-34), teaches that their crystal of R(+)-lansoprazole is formed from amorphous R(+)-lansoprazole (on pages 13-19, Fujishima provides working examples to form the crystal of R(+)-lansoprazole; on pages 13-15, Fujishima provides two reference examples for the preparation of the starting material, where lansoprazole (racemate) is dissolved in an organic solvent containing an organic base, fractionated, concentrated, dissolved in an organic solvent, filtered, concentrated, and dried to yield R(+)-lansoprazole as an amorphous substance; on pages 15-19, Fujishima provides two examples for the preparation of the crystal of R(+)-lansoprazole by using the amorphous R(+)-lansoprazole obtained in the two reference examples on pages 13-15), and teaches that their resulting crystal of R(+)-lansoprazole can be a hydrate (see Example 3 on page 18). Thus, contrary to the

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rejection's position, Fujishima is far from teaching that their crystal of R(+)-lansoprazole is the starting material, let alone that the hydrate form of their crystal of R(+)-lansoprazole can be used as the starting material.

The rejection contends that Fujishima teaches the evaporation of a hydrate of R(+)-lansoprazole to dryness, and therefore, one of ordinary skill in the art would manipulate the parameters controlling the dryness, such as temperature, during the process of routine experimentation and produce the amorphous R(+)-lansoprazole. However, as indicated above, Fujishima teaches that their targeted product is the crystal of R(+)-lansoprazole, and the starting material used to obtain the crystal of R(+)-lansoprazole is the amorphous R(+)-lansoprazole. On the other hand, the method of claim 23 involves just the opposite. That is, claim 23 involves producing an amorphous optically active isomer of lansoprazole from hydrated crystals of optically active isomer (R-isomer) of lansoprazole. Accordingly, claim 23 and its dependent claims are patentable over Fujishima.

Claim 27 recites that the produced amorphous optically active isomer of lansoprazole does not show a specific peak under an X-ray powder diffraction analysis. Claim 28 recites that the hydrated crystals show a specific peak under an X-ray powder diffraction analysis, and keeping the hydrated crystals includes drying the hydrated crystals at about 60°-70° C under reduced pressure. Claim 29 recites that the hydrated crystals exhibit a specific peak under an X-ray powder diffraction analysis, and keeping the hydrated crystals includes drying the hydrated crystals at about 65° C under ventilation. Claim 30 recites that the produced amorphous optically active isomer of lansoprazole contains more amorphous form than crystalline form. Claim 31 recites that the produced amorphous optically active isomer of lansoprazole contains about 60% or more amorphous form. Hashimoto and Fujishima do not teach or suggest the features of claims 27-31. Therefore, claims 27-31 are further removed from the references.

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In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

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Respectfully submitted,

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